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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,176	11/30/2006	Howard J. Smith	P1119/20001	5589
58478	7590	06/02/2010	EXAMINER	
BIO INTELLECTUAL PROPERTY SERVICES (BIO IPS) LLC 8509 KERNON CT. LORTON, VA 22079				LUCAS, ZACHARIAH
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,176	SMITH, HOWARD J.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 September 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5,6,9-22,27,29-31,33,36 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,5,6,9-22,27,29-31,33,36 and 38-43 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Claims 1, 5, 6, 9-22, 27, 29-31, 33, 36, and 38-43 are pending and under consideration in the application.
2. In the prior action, the Final action mailed on October 22, 2008, claims 1, 5, 6, 9-23, 27, 29-31, 33, 36, 38-43 were pending and rejected.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2009 has been entered.
4. In the amendment of February 23, 2009, the Applicant cancelled claim 23; and amended claim 33.
5. The period for suspension of action by the Office, in view of the granting of the petitions of February 23 and September 11, 2009, has run.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on February 23, 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 101

7. **(Prior Rejection- Withdrawn)** Claim 32 was rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an

improper definition of a process. In view of the cancellation of the claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

8. **(Prior Rejection- Withdrawn)** Claims 33, 36, 38-42 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment of the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Maintained)** Claims 1, 9-23, 27, 33, and 38-43 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ganguly et al. (WO 00/23455). The rejection is withdrawn from cancelled claim 23.

Applicant traverses the rejection on three grounds.

First, Applicant refers to certain teachings on page 39 of the reference. However, the arguments based on these teachings fail to consider the teachings in the reference as a whole. In particular, the Applicant is directed to the teachings on page 34-35 if the reference with respect to the range of potential dosages and modes of administration of such as described in the prior

actions. In view of the presence of such teachings, the Applicant's arguments based solely on the teachings of page 39 are not found persuasive.

Second, Applicant again asserts that the teachings of the reference do not disclose or suggest the benefits with respect to the claimed mode of administration and dosage. Again, it is noted that the Applicant has not presented any evidence to support the assertion that such a benefit is actually achieved. While the Applicant has indicated on page 7 of the response that studies to provide data in support of the assertion are under investigation, such indications fail to provide actual support for the assertions until such data is actually provided.

The Applicant finally asserts that the teachings of other reference teach that the acceptable daily dosages of ribavirin are between 800 and 1200 mg/day. These arguments are not found persuasive. First, it is noted that the teachings of these references cited by the Applicant (on page 10 of the Response) appear to be based upon patients with particular body weights. It is noted that the Applicant has provided only the abstracts of these references. Second, the teachings of Ganguly identify additional factors that may be considered. Finally, the teachings of Ganguly specifically indicate that the use of dosages of 200-1600 or 400-800 **mg/day**, thus indicating that the use of dosages of less than 400 mg/day were contemplated by the reference. Because the reference suggests the use of dosages as low as 200 mg/day, and specifies that this is a daily dose, the reference clearly intended that the lower dosages represent more than merely a part of a multi-dose daily treatment. Applicant's arguments on these grounds are therefore also not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

(Prior Rejection- Maintained) Claims 5, 6, and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly as applied to claims 1-4, 7-28, 32-35, 37-43 above, and further in view of Wong et al. (U.S. 6,120,803). Applicant's arguments in traversal of the present rejection are substantially the same as those presented with respect to the rejection over the Ganguly reference alone as described above, with additional assertions indicating that the teachings of Wong fail to address the asserted deficiencies of the Ganguly reference. As the arguments with respect to Ganguly are not found persuasive for the reasons indicated above, the arguments with respect to the present rejection are similarly not found persuasive. This rejection is therefore also maintained for the reasons above, and the reasons of record.

11. **(Prior Rejection- Maintained)** Claims 29-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly as applied to claims 1-4, 7-28, 32-35, 37-43 above, and further in view of the teachings of Wong (*supra*) and Brass et al. (US 6849524). No additional argument is made specifically addressing this rejection except that the teachings of Bass fail to overcome the asserted deficiencies of the references cited above. The rejection is therefore maintained for the reasons above, and the reasons of record.

Double Patenting

12. **(Warning- Withdrawn)** Applicant was advised that should claim 1 (as amended) be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. In view of the cancellation of claim 23, the warning is now moot.

Conclusion

13. No claims are allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648